

Centre of Product and Cosmetics Evaluation

National Pharmaceutical Regulatory Agency (NPRA)
Lot 36, Jalan Universiti (Jalan Profesor Diraja Ungku Aziz),
46200 Petaling Jaya,
Selangor, Malaysia.

14 March 2025

Dear Sir/ Madam,

RE: Letter of Commitment to Submit Variation for Label update

The above subject matter is referred.

We, Vantive Sdn Bhd., hereby commit to submit variation to update labels with revised MAL number after approval of current variation is obtained. The reason is that the labels are shared among other countries including Singapore, Brunei, Hong Kong and Taiwan. Hence, the process needed to obtain the updated label is time consuming.

Additionally, we are submitting a list of variations including CCDS update which is needed to submit urgently.

This commitment applied for following products listed below with respective registration number Malaysia.

Product Name	Registration No.
REGIOCIT SOLUTION FOR HAEMOFILTRATION	MAL18066047AZ
Phoxilium 1.2 mmol/l phosphate solution for haemodialysis/haemofiltration	MAL19116023AZ
Biphozyl Solution for haemodialysis/haemofiltration	MAL18086101AZ

We sincerely apologize for the inconvenience caused and appreciate your understanding on this matter.

Should you require further information on this request, please do not hesitate to contact me.

Thank you.

Yours sincerely,



Electronically signed by: Kai Xin
Lim
Reason: I am the author of this
document
Date: Mar 17, 2025 14:13 GMT+8

Lim Kai Xin
Regulatory Affairs Specialist
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